

§ 211.208

investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity. A drug product may be reprocessed provided the subsequent drug product meets appropriate standards, specifications, and characteristics. Records of returned drug products shall be maintained and shall include the name and label potency of the drug product dosage form, lot number (or control number or batch number), reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned drug product. If the reason for a drug product being returned implicates associated batches, an appropriate investigation shall be conducted in accordance with the requirements of § 211.192. Procedures for the holding, testing, and reprocessing of returned drug products shall be in writing and shall be followed.

§ 211.208 Drug product salvaging.

Drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures shall not be salvaged and returned to the marketplace. Whenever there is a question whether drug products have been subjected to such conditions, salvaging operations may be conducted only if there is (a) evidence from laboratory tests and assays (including animal feeding studies where applicable) that the drug products meet all applicable standards of identity, strength, quality, and purity and (b) evidence from inspection of the premises that the drug products and their associated packaging were not subjected to improper storage conditions as a result of the disaster or accident. Organoleptic examinations shall be acceptable only as supplemental evidence that the drug products meet appropriate standards of identity, strength, quality, and purity. Records including name, lot number, and disposition shall be maintained for drug products subject to this section.

21 CFR Ch. I (4–1–10 Edition)

PART 212—CURRENT GOOD MANUFACTURING PRACTICE FOR POSITRON EMISSION TOMOGRAPHY DRUGS (Eff. 12-12-2011)

Subpart A—General Provisions

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- 212.1 What are the meanings of the technical terms used in these regulations?
- 212.2 What is current good manufacturing practice for PET drugs?
- 212.5 To what drugs do the regulations in this part apply?

Subpart B—Personnel and Resources

- 212.10 What personnel and resources must I have?

Subpart C—Quality Assurance

- 212.20 What activities must I perform to ensure drug quality?

Subpart D—Facilities and Equipment

- 212.30 What requirements must my facilities and equipment meet?

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- 212.40 How must I control the components I use to produce PET drugs and the containers and closures I package them in?

Subpart F—Production and Process Controls

- 212.50 What production and process controls must I have?

Subpart G—Laboratory Controls

- 212.60 What requirements apply to the laboratories where I test components, in-process materials, and finished PET drug products?
- 212.61 What must I do to ensure the stability of my PET drug products through expiry?

Subpart H—Finished Drug Product Controls and Acceptance Criteria

- 212.70 What controls and acceptance criteria must I have for my finished PET drug products?
- 212.71 What actions must I take if a batch of PET drug product does not conform to specifications?